I claim:

1. A method of determining whether an immunization schedule affects the incidence, prevalence, frequency or severity of a chronic immune-mediated disorder in at least one treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in at least one treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence or frequency of said chronic immune-mediated disorder in the treatment group, with that in the control group;

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where said chronic immune-mediated disorder is diabetes, and said mammals are human;

wherein the control and treatment group differ by at least one of the following differences:

a) the presence of at least one immunogen in the schedule for one group and not the other;
b) a difference in the size of the dose of at least one immunogen administered to both groups;
c) a difference in the number of doses of at least one immunogen administered to both groups; or
d) a difference in the day of administration, relative to birth, of the first dose of at least one immunogen administered to both groups; and

wherein the effect of the schedule on the incidence, prevalence, or frequency of the disorder is observed at least one year after the first difference in immunization between the groups is manifest.

2. The method of claim 1 where at least one of said differences (a)-(d) relates to at least one immunogen other than a BCG immunogen.

3. The method of claim 1 where at least one of said differences (a)-(d) relates to at least one immunogen other than a BCG or measles immunogen.

4. The method of claim 1 where at least one of said differences (a)-(d) relates to at least one immunogen other than a BCG, measles, mumps, rubella, smallpox, diphtheria, tetanus, pertussis or polio immunogen.

5. The method of claim 3 where at least difference (a) applies.

6. The method of claim 3 where at least difference (b) applies.

7. The method of claim 3 where at least difference (c) applies.

8. The method of claim 3 where at least difference (d) applies.

9. The method of claim 3 where at least two of differences (a)-(d) apply.

10. The method of claim 3 where at least three of differences (a)-(d) apply.

11. The method of claim 1 where all of differences (a)-(d) apply.

12. The method of claim 1 which further comprises determining whether an immunization schedule slows the onset of diabetes as evidenced by a reduction of the incidence of diabetes in one of said groups relative to another of said groups, as determined at a particular time or times after birth.

13. The method of claim 1, where at least one observation of the effect of the schedules is made at least three years after said first difference in immunization of said mammals.

14. The method of claim 1, where at least one of the following conditions applies

i) the first dose of said immunization schedule is given in at least one group when the mammals are less than 42

days old,

ii) said immunization schedule protects against at least two infectious diseases,

iii) the ability of said immunogen or immunization schedule to prevent an infectious disease is also tested,

iv) the treatment and control groups differ as to the presence, dosage, timing or composition of at least one immunogen which is other than a live vaccine,

v) said immunogen is one other than a pertussis immunogen,

vi) the method is part of a development process or clinical trial of a vaccine to test a vaccine for safety or efficacy,

vii) the method is prospective,

viii) said mammals are randomized in said treatment and control groups,

ix) at least one said treatment group receives one potentially pharmaceutically acceptable dose of at least two potentially pharmaceutically acceptable immunogenic agents which comprise at least one potentially pharmaceutically acceptable first pediatric immunogen and at least one agent selected from the group consisting of a second pediatric immunogen and a non-pediatric immunogen,

x) at least one immunogen being studied for its effect on the incidence or severity of said disorder is administered starting after 41 days but before 180 days of life,

xi) at least the majority of the mammals in the control group did not develop the infectious diseases which are prevented by said immunogen,

xii) mammals are excluded from a treatment group if at

least one of conditions (aa)-(cc) applies:

aa) said mammals have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or

bb) said mammals have substantial levels of at least one surrogate marker of an autoimmune disease even though the mammals had not been previously diagnosed as having an autoimmune disease, or

cc) said surrogate marker was substantially increased following a previous vaccination, infection or other immunologic challenge

xiii) at least one observation of the effect of the schedules occurs at least five years after the birth of the mammals

xiv) at least one chronic immune-mediated disorder in addition to diabetes is compared,

xv) at least one immunogen administered to the treatment group is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, Japanese encephalitis, flavirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens

xvi) it is determined whether the age of the subject mammal, at the time of commencement of the immunization schedule, affects the incidence, prevalence or frequency of the disorder,

xvii) the incidence of the disorder in the treatment group is compared to the incidence of the disorder in the control group, or

xviii) in at least one group both a pediatric immunogen and a non-pediatric immunogen are administered.

15. The method of claim 14 where condition (i), condition (xv) and at least one of the conditions (ii)-(xiv) and (xvi-(xviii) applies.

16. The method of claim 15 where at least two of conditions (ii)-(xiv) and (xvi)-(xviii) apply.

17. The method of claim 15 where at least three of conditions (ii)-(xiv) and (xvi)-(xviii) apply.

18. The method of claim 15 where at least four of conditions (ii)-(xiv) and (xvi)-(xviii) apply.

19. The method of claim 15 where at least five of conditions (ii)-(xiv) and (xvi)-(xviii) apply.

20. The method of claim 15 where at least six of conditions (ii)-(xiv) and (xvi)-(xviii) apply.

21. The method of claim 15 where at least seven of conditions (ii)-(xiv) and (xvi)-(xviii) apply.

22. The method of claim 15 where at least eight of conditions (ii)-(xiv) and (xvi)-(xviii) apply.

23. The method of claim 15 where at least nine of conditions (ii)-(xiv) and (xvi)-(xviii) apply.

24. The method of claim 15 where at least ten of conditions (ii)-(xiv) and (xvi)-(xviii) apply.

25. The method of claim 15 where at least eleven of conditions (ii)-(xiv) and (xvi)-(xviii) apply.

26. The method of claim 15 where at least twelve of

conditions (ii)-(xiv) and (xvi)-(xviii) apply.

27. The method of claim 15 where at least thirteen of conditions (ii)-(xiv) and (xvi)-(xviii) apply.

28. The method of claim 14 where conditions (x) and (xv), and at least one of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) applies.

29. The method of claim 28 where at least two of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

30. The method of claim 28 where at least three of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

31. The method of claim 28 where at least four of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

32. The method of claim 28 where at least five of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

33. The method of claim 28 where at least six of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

34. The method of claim 28 where at least seven of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

35. The method of claim 28 where at least eight of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

36. The method of claim 28 where at least nine of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

37. The method of claim 28 where at least ten of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

38. The method of claim 28 where at least eleven of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

39. The method of claim 28 where at least twelve of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

40. The method of claim 28 where at least thirteen of

conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

41. The method of claim 28 where at least fourteen of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

42. The method of claim 28 where at least fifteen of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

43. The method of claim 28 where all sixteen of conditions (i)-(ix), (xi)-(xiv) and (xvi)-(xviii) apply.

44. The method of claim 3 where the following condition applies

i) the first dose of said immunization schedule is given in at least one group when the mammals are less than 42 days old.

45. The method of claim 3 where the following condition applies

ii) said immunization schedule prevents at least one infectious disease.

46. The method of claim 3 where the following condition applies

iii) the ability of said immunogen or immunization schedule to prevent an infectious disease is also tested.

47. The method of claim 3 where the following condition applies

iv) the treatment and control groups differ as to the presence, dosage, timing or composition of at least one immunogen which is other than a live vaccine.

48. The method of claim 3 where the following condition applies

v) said immunogen is one other than a pertussis immunogen.

49. The method of claim 3 where the following condition applies

vi) the method is part of a development process or clinical trial of a vaccine to test a vaccine for safety or efficacy.

50. The method of claim 3 where the following condition applies

vii) the method is prospective.

51. The method of claim 3 where the following condition applies

viii) said mammals are randomized in said treatment and control groups.

52. The method of claim 3 where the following condition applies

ix) at least one said treatment group receives one potentially pharmaceutically acceptable dose of at least two potentially pharmaceutically acceptable immunogenic agents which comprise at least one potentially pharmaceutically acceptable first pediatric immunogen and at least one agent selected from the group consisting of a second pediatric immunogen and a non-pediatric immunogen.

53. The method of claim 3 where the following condition applies

x) at least one immunogen being studied for its effect on the incidence or severity of said disorder is administered starting after 41 days but before 180 days of life.

54. The method of claim 3 where the following condition applies

xi) at least the majority of the mammals in the control group did not develop the infectious diseases which are

prevented by said immunogen.

55. The method of claim 3 where the following condition applies

xii) mammals are excluded from a treatment group if at least one of conditions (aa)-(cc) applies:

aa) said mammals have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or

bb) said mammals have substantial levels of at least one surrogate marker of an autoimmune disease even though the mammals had not been previously diagnosed as having an autoimmune disease, or

cc) said surrogate marker was substantially increased following a previous vaccination, infection or other immunologic challenge.

56. The method of claim 3 where the following condition applies

xiii) at least one observation of the effect of the schedules occurs at least five years after the birth of the mammals.

57. The method of claim 3 where the following condition applies

xiv) at least one chronic immune-mediated disorder in addition to diabetes is compared.

58. The method of claim 3 where the following condition applies

xv) at least one immunogen administered to the treatment group is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis,

pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, Japanese encephalitis, flavirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

59. The method of claim 3 where the following condition applies

xvi) it is determined whether the age of the subject mammal, at the time of commencement of the immunization schedule, affects the incidence, prevalence or frequency of the disorder.

60. The method of claim 3 where the following condition applies

xvii) the incidence of the disorder in the treatment group is compared to the incidence of the disorder in the control group.

61. The method of claim 3 where the following condition applies

xviii) in at least one group both a pediatric immunogen and a non-pediatric immunogen are administered.

62. The method of claim 3 where at least one of the following conditions applies:

i) the first dose of said immunization schedule is given when the mammals are less than 42 days old,

ii) said immunization schedule prevents at least one infectious disease,

iii) the ability of said immunogen or immunization schedule to prevent an infectious disease is also tested,

iv) the treatment and control groups differ as to the presence, dosage, timing or composition of at least one immunogen which is other than a live vaccine.

63. The method of claim 62 where at least two of conditions (i)-(iv) apply.

64. The method of claim 62 where at least three of conditions (i)-(iv) apply.

65. The method of claim 62 where all four of conditions (i)-(iv) apply.

66. The method of claim 1 where the following conditions apply:

iii) the ability of said immunogen or immunization schedule to prevent an infectious disease is also tested,

vii) the method is prospective,

viii) said mammals are randomized in said treatment and control groups,

xiv) at least one chronic immune-mediated disorder in addition to diabetes is compared.

67. The method of claim 66 where the following condition applies:

i) the first dose of said immunization schedule is given when the mammals are less than 42 days old.

68. The method of claim 67 where the following condition applies:

xv) at least one immunogen administered to the treatment group is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease,

cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, Japanese encephalitis, flavirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

69. The method of claim 67 where the following conditions apply:

iv) the treatment and control groups differ as to the presence, dosage, timing or composition of at least one immunogen which is other than a live vaccine,

v) said immunogen is one other than a pertussis immunogen.

70. The method of claim 67 where the following condition applies:

xiii) at least one observation of the effect of the schedules occurs at least five years after the birth of the mammals.

71. The method of claim 67 where the following condition applies:

x) at least one immunogen being studied for its effect on the incidence or severity of said disorder is administered starting after 41 days but before 180 days of life.

72. The method of claim 71 where the following condition applies:

xv) at least one immunogen administered to the treatment group is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever,

streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, Japanese encephalitis, flavirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens

73. The method of claim 66 where the following condition applies:

x) at least one immunogen being studied for its effect on the incidence or severity of said disorder is administered starting after 41 days but before 180 days of life.

74. The method of claim 73 where the following condition applies:

xv) at least one immunogen administered to the treatment group is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, Japanese encephalitis, flavirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

75. The method of claim 73 where the following conditions apply:

iv) the treatment and control groups differ as to the presence, dosage, timing or composition of at least one immunogen which is other than a live vaccine,

v) said immunogen is one other than a pertussis immunogen.

76. The method of claim 73 where the following condition applies:

xiii) at least one observation of the effect of the schedules occurs at least five years after the birth of the mammals.

77. The method of claim 1 where the following conditions apply:

i) the first dose of said immunization schedule is given in at least one group when the mammals are less than 42 days old,

ii) said immunization schedule prevents at least one infectious disease,

v) said immunogen is one other than a pertussis immunogen.

78. The method of claim 77 where the following condition applies:

xviii) in at least one group both a pediatric immunogen and a non-pediatric immunogen are administered.

79. The method of claim 1 where the following conditions apply:

i) the first dose of said immunization schedule is given in at least one group when the mammals are less than 42 days old,

ii) said immunization schedule prevents at least one infectious disease,

xvi) it is determined whether the age of the subject mammal, at the time of commencement of the immunization schedule, affects the incidence, prevalence or frequency of the disorder.

80. The method of claim 1 where the following conditions apply:

i) the first dose of said immunization schedule is given in at least one group when the mammals are less than 42 days old,

xviii) in at least one group both a pediatric immunogen and a non-pediatric immunogen are administered.

81. The method of claim 79 where the following condition applies:

xiii) at least one observation of the effect of the schedules occurs at least five years after the birth of the mammals.

82. The method of claim 80 where the following conditions apply:

ii) said immunization schedule prevents at least one infectious disease,

xiii) at least one observation of the effect of the schedules occurs at least five years after the birth of the mammals.

83. The method of claim 1 where the following conditions apply:

i) the first dose of said immunization schedule is given in at least one group when the mammals are less than 42 days old,

iv) the treatment and control groups differ as to the presence, dosage, timing or composition of at least one immunogen which is other than a live vaccine,

xiii) at least one observation of the effect of the schedules occurs at least five years after the birth of the mammals.

84. The method of claim 1 where the following conditions

apply:

i) the first dose of said immunization schedule is given in at least one group when the mammals are less than 42 days old,

iv) the treatment and control groups differ as to the presence, dosage, timing or composition of at least one immunogen which is other than a live vaccine,

xvi) it is determined whether the age of the subject mammal, at the time of commencement of the immunization schedule, affects the incidence, prevalence or frequency of the disorder.

85. The method of claim 1 where the following conditions apply:

i) the first dose of said immunization schedule is given in at least one group when the mammals are less than 42 days old,

iv) the treatment and control groups differ as to the presence, dosage, timing or composition of at least one immunogen which is other than a live vaccine,

v) said immunogen is one other than a pertussis immunogen,

xiii) at least one observation of the effect of the schedules occurs at least five years after the birth of the mammals.

86. The method of claim 1 where the following conditions apply:

i) the first dose of said immunization schedule is given in at least one group when the mammals are less than 42 days old,

x) at least one immunogen being studied for its effect on the incidence or severity of said disorder is administered starting after 41 days but before 180 days

of life,

ii) said immunization schedule prevents at least one infectious disease,

v) said immunogen is one other than a pertussis immunogen.

87. The method of claim 86 where the following condition also applies:

xviii) in at least one group both a pediatric immunogen and a non-pediatric immunogen are administered.

88. The method of claim 1 where the following conditions apply:

x) at least one immunogen being studied for its effect on the incidence or severity of said disorder is administered starting after 41 days but before 180 days of life,

ii) said immunization schedule prevents at least one infectious disease,

v) said immunogen is one other than a pertussis immunogen.

89. The method of claim 1 where the following conditions apply:

x) at least one immunogen being studied for its effect on the incidence or severity of said disorder is administered starting after 41 days but before 180 days of life,

iv) the treatment and control groups differ as to the presence, dosage, timing or composition of at least one immunogen which is other than a live vaccine,

xiii) at least one observation of the effect of the schedules occurs at least five years after the birth of the mammals.

90. The method of claim 89 where the following condition also applies:

v) said immunogen is one other than a pertussis immunogen.

91. The method of claim 1 where the following conditions apply:

x) at least one immunogen being studied for its effect on the incidence or severity of said disorder is administered starting after 41 days but before 180 days of life,

iv) the treatment and control groups differ as to the presence, dosage, timing or composition of at least one immunogen which is other than a live vaccine,

v) said immunogen is one other than a pertussis immunogen,

xvi) it is determined whether the age of the subject mammal, at the time of commencement of the immunization schedule, affects the incidence, prevalence or frequency of the disorder.

92. The method of claim 91 where the following condition also applies:

vi) the method is part of a development process or clinical trial of a vaccine to test a vaccine for safety or efficacy.

93. The method of claim 1 where the following conditions apply:

x) at least one immunogen being studied for its effect on the incidence or severity of said disorder is administered starting after 41 days but before 180 days of life,

iv) the treatment and control groups differ as to the presence, dosage, timing or composition of at least one

immunogen which is other than a live vaccine,

v) said immunogen is one other than a pertussis immunogen,

xvi) it is determined whether the age of the subject mammal, at the time of commencement of the immunization schedule, affects the incidence, prevalence or frequency of the disorder,

vi) the method is part of a development process or clinical trial of a vaccine to test a vaccine for safety or efficacy,

xv) at least one immunogen administered to the treatment group is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, Japanese encephalitis, flavirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

94. The method of claim 93 where the following condition also applies:

xiii) at least one observation of the effect of the schedules occurs at least five years after the birth of the mammals.

95. The method of claim 94 where the following condition also applies

i) the first dose of said immunization schedule is given in at least one group when the mammals are less than 42 days old.

96. The method of claim 1 where the following conditions apply:

x) at least one immunogen being studied for its effect on the incidence or severity of said disorder is administered starting after 41 days but before 180 days of life,

ii) said immunization schedule prevents at least one infectious disease,

iv) the treatment and control groups differ as to the presence, dosage, timing or composition of at least one immunogen which is other than a live vaccine.

97. A method of determining whether an immunization schedule affects the incidence, prevalence or frequency of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, or frequency of said chronic immune-mediated disorder, in the treatment group, with that in the control group,

wherein said chronic immune mediated disorder is a diabetes mellitus which has not been chemically induced by streptozotocin,

wherein said immunogen is one other than a BCG immunogen, wherein the mammal is an animal model for human diabetes, and where the control and the treatment group differ by at least one of the following:

(a) the presence of at least one immunogen,
(b) the size of the dose of at least one immunogen,
(c) the number of doses of at least one immunogen, or
(d) the timing of administration of the first dose of at least one immunogen.

98. The method of claim 97 in which

(i) the first dose is given to at least one group when the mammals are less than 42 days old,

99. The method of claim 97 where at least one of the following limitations applies:

i) the first dose is given to at least one group when the mammals are less than 42 days old,

ii) said immunization schedule protects against at least two infectious diseases if administered to humans,

iii) at least one immunogen is administered by a route other than intravenously,

iv) at least one immunogen is one other than a live vaccine,

v) said immunogen is one other than a pertussis immunogen,

vi) the method is part of a development process to test a vaccine for efficacy or safety,

vii) it is determined whether the age of the subject mammal, at the time of commencement of the immunization schedule, affects the incidence, prevalence or frequency of the disorder,

viii) at least one group receives more than one dose of at least one immunogen in a plurality of doses of said immunogen,

ix) at least one said treatment group receives one potentially pharmaceutically acceptable dose of each of at least two potentially pharmaceutically acceptable immunogenic agents, which comprise at least one potentially pharmaceutically acceptable first pediatric immunogen and at least one agent selected from the group consisting of a second pediatric immunogen and a nonpediatric immunogen,

x) at least one immunogen being studied for its effect

on the incidence, prevalence or frequency of said disorder is administered starting after 41 days but before 180 days of life,

xi) the method is part of a production process to test vaccine lots for efficacy or safety,

xii) said mammals are NOD mice or BB rats,

xiii) the mammals are rodents and the groups are compared from first administration until at least 24.5 weeks of age,

xiv) at least a second chronic immune-mediated disorder in addition to diabetes is so compared, and said second disorder is an autoimmune disease,

xv) at least one group receives an immunogen starting after 41 days of life,

xvi) at least one immunogen is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, Japanese encephalitis, flavirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens

xvii) said groups have not received an autoantigen capable of inducing diabetes,

xviii) at least two pediatric immunogens are administered to at least one group,

xvix) the mammals are made susceptible to said immune-mediated disorder by administration of an

immunosuppressant or by immunosuppressive surgery,

xx) the mammals are rodents and the groups are compared from first administration until at least 52 days after the last administration of an immunogen according to the immunization schedules for said groups,

xxi) the level of an autoantibody marker in two groups is compared,

xxii) at least one immunogen is administered with a depot adjuvant,

xxiii) a dose of immunogen being administered is a pharmaceutically acceptable dose or a dose indicating that a pharmaceutically acceptable dose would reduce said incidence or severity of said disorder or the level of a marker of such a disorder,

xxiv) the mammals are rodents.

100. The method of claim 97 in which

vii the first dose is given when the mammals are less than 14 days old.

101. The method of claim 99 where at least 2 conditions apply.

102. The method of claim 99 where at least 3 conditions apply.

103. The method of claim 99 were at least 4 conditions apply.

104. The method of claim 99 were at least 5 conditions apply.

105. The method of claim 99 were at least 6 conditions apply.

106. The method of claim 99 were at least 7 conditions apply.

107. The method of claim 99 where at least 8 conditions apply.

108. The method of claim 99 where at least 9 conditions apply.

109. The method of claim 99 where at least 10 conditions apply.

110. The method of claim 99 where at least 11 conditions apply.

111. The method of claim 99 where at least 13 conditions apply.

112. The method of claim 99 where at least 14 conditions apply.

113. The method of claim 99 where at least 15 conditions apply.

114. The method of claim 99 were at least 16 conditions apply.

115. The method of claim 99 were at least 17 conditions apply.

116. The method of claim 99 were at least 18 conditions apply.

117. The method of claim 99 were at least 19 conditions apply.

118. The method of claim 99 where at least 20 conditions apply.

119. The method of claim 99 where at least 21 conditions apply.

120. The method of claim 99 where at least 22 conditions apply.

121. The method of claim 99 where at least 23 conditions

apply.

122. The method of claim 99 where at least 24 conditions apply.

123. The method of claim 97 where the following conditions apply:

i) the first dose is given to at least one group when the mammals are less than 42 days old,

ii) said immunization schedule involves administration of immunogens capable of protecting against at least one infectious disease in humans,

iv) at least one immunogen is one other than a live vaccine,

v) said immunogen is one other than a pertussis immunogen.

124. The method of claim 123 where the following condition applies:

viii) at least one group receives more than one dose of at least one immunogen in a plurality of doses of said immunogen.

125. The method of claim 123 where the following condition applies:

x) at least one immunogen being studied for its effect on the incidence, prevalence or frequency of said disorder is administered starting after 41 days but before 180 days of life.

126. The method of claim 123 where the following condition applies:

xxiii) a dose of immunogen being administered is a pharmaceutically acceptable dose or a dose indicating that a pharmaceutically acceptable dose would reduce said incidence or severity of said disorder or the level of a

marker of such a disorder,

127. The method of claim 123 where the following condition applies:

xxiv) the mammals are rodents.

128. The method of claim 127 where the following condition applies:

xii) said mammals are NOD mice or BB rats.

129. The method of claim 123 where the following condition applies:

xiii) the mammals are rodents and the groups are compared from first administration until at least 24.5 weeks of age.

130. The method of claim 123 where the following condition applies:

xx) the mammals are rodents and the groups are compared from first administration until at least 52 days after the last administration of an immunogen according to the immunization schedules for said groups.

131. The method of claim 123 where the following condition applies:

vi) the method is part of a development process to test a vaccine for efficacy or safety.

132. The method of claim 123 where the following condition applies:

xi) the method is part of a production process to test vaccine lots for efficacy or safety.

133. The method of claim 123 where the following condition applies:

xvi) at least one immunogen is selected from the group

consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, chytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenze, parainfluenze, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavirus, dengue toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

134. The method of claim 123 where the following condition applies:

iii) at least one immunogen is administered by a route other than intravenously.

135. The method of claim 123 where the following conditions apply:

xiii) the mammals are rodents and the groups are compared from first administration until at least 24.5 weeks of age,

xvi) at least one immunogen is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, chytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenze, parainfluenze, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavirus, dengue toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

136. The method of claim 135 where the following

condition applies:

viii) at least one group receives more than one dose of at least one immunogen in a plurality of doses of said immunogen.

137. The method of claim 135 where the following condition applies:

x) at least one immunogen being studied for its effect on the incidence, prevalence or frequency of said disorder is administered starting after 41 days but before 180 days of life.

138. The method of claim 135 where the following condition applies:

xii) said mammals are NOD mice or BB rats.

139. The method of claim 135 where the following condition applies:

xx) the mammals are rodents and the groups are compared from first administration until at least 52 days after the last administration of an immunogen according to the immunization schedules for said groups.

140. The method of claim 135 where the following condition applies:

xi) the method is part of a production process to test vaccine lots for efficacy or safety.

141. The method of claim 135 where the following condition applies:

iii) at least one immunogen is administered by a route other than intravenously.

142. The method of claim 135 where the following condition applies:

ix) at least one said treatment group receives one

potentially pharmaceutically acceptable dose of each of at least two potentially pharmaceutically acceptable immunogenic agents, which comprise at least one potentially pharmaceutically acceptable first pediatric immunogen and at least one agent selected from the group consisting of a second pediatric immunogen and a nonpediatric immunogen.

143. The method of claim 123 where the following condition applies

ix) at least one said treatment group receives one potentially pharmaceutically acceptable dose of each of at least two potentially pharmaceutically acceptable immunogenic agents, which comprise at least one potentially pharmaceutically acceptable first pediatric immunogen and at least one agent selected from the group consisting of a second pediatric immunogen and a nonpediatric immunogen.

144. The method of claim 125 where the following condition applies

ix) at least one said treatment group receives one potentially pharmaceutically acceptable dose of each of at least two potentially pharmaceutically acceptable immunogenic agents, which comprise at least one potentially pharmaceutically acceptable first pediatric immunogen and at least one agent selected from the group consisting of a second pediatric immunogen and a nonpediatric immunogen.

145. The method of claim 128 where the following condition applies

ix) at least one said treatment group receives one potentially pharmaceutically acceptable dose of each of at least two potentially pharmaceutically acceptable immunogenic agents, which comprise at least one potentially pharmaceutically acceptable first pediatric immunogen and at least one agent selected from the group consisting of a second pediatric immunogen and a nonpediatric immunogen.

146. The method of claim 137 where the following condition applies

ix) at least one said treatment group receives one potentially pharmaceutically acceptable dose of each of at least two potentially pharmaceutically acceptable immunogenic agents, which comprise at least one potentially pharmaceutically acceptable first pediatric immunogen and at least one agent selected from the group consisting of a second pediatric immunogen and a nonpediatric immunogen.

147. The method of claim 138 where the following condition applies

ix) at least one said treatment group receives one potentially pharmaceutically acceptable dose of each of at least two potentially pharmaceutically acceptable immunogenic agents, which comprise at least one potentially pharmaceutically acceptable first pediatric immunogen and at least one agent selected from the group consisting of a second pediatric immunogen and a nonpediatric immunogen.

148. The method of claim 1 wherein at least one of said immunization schedules protects against at least one infectious disease.

add cl7

add D2